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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,035	06/25/2003	Clarence Nathaniel Ahlem	202.2D4	6394

26551 7590 10/21/2005

HOLLIS-EDEN PHARMACEUTICALS, INC.
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EXAMINER

BADIO, BARBARA P

ART UNIT PAPER NUMBER

1617

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,035	AHLEM ET AL.	
	Examiner	Art Unit	
	Barbara P. Badio, Ph.D.	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50 and 54-84 is/are pending in the application.
- 4a) Of the above claim(s) 54,56,58,60,63,65 and 67-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 50,55,57,59,61,62,64,66 and 77-84 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/15/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

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Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

2. Applicant traverse the restriction requirement because a search of the claimed compounds wherein R⁸ and R⁹ include –O- or –NH- would not impose an undue search burden on the Office since there are search engines that would allow inclusion of heteroatom at selected positions in heterocyclic compounds. This is not found persuasive because in addition to imposing a serious burden on the examiner, the proposed scope of compounds includes inventions that are both independent and distinct (see MPEP § 803). The examiner notes the various classes and numerous subclasses as indicated in the Office Action dated September 9, 2004. Therefore, a search of the full scope of compounds as suggested by applicant would impose a serious burden on the examiner.

The requirement is still deemed proper and is therefore made **FINAL**.

Double Patenting

3. The provisional rejections of (a) claims 50, 57, 61 and 62 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 10/607,415; (b) claims 50, 55, 57, 59, 61, 62, 64 and 66

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under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 10/728,400 and (c) claims 50, 57, 61, 62 and 66 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 10/949,694 are maintained and claims 77-84 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims of copending Applications No. 10/607,415; 10/728,400 and 10/949,694.

Applicant's statement that the provisional rejections be held in abeyance is noted.

Claim Rejections - 35 USC § 102

4. The rejection of claims 50 and 57 under 35 USC 102(b) over Daynes et al. (US 5,532,230) is withdrawn.

Claim Rejections - 35 USC § 103

5. The rejection of claims 50, 55, 57 and 59 under 35 USC 103(a) over Daynes et al. (US 5,532,230) is maintained.

Applicant argues the reference discloses the use of compounds for treating acute clinical conditions and not chronic condition such as asthma. Applicant's argument was considered but not persuasive for the following reason.

The instant claims are drawn to treatment or amelioration of inflammatory conditions. The cited prior art teaches the reduction of adult respiratory distress

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syndrome (see especially col. 8, lines 27-33). Inflammatory conditions include both asthma, as stated by applicant, and allergic respiratory disease, which includes adult respiratory distress syndrome as taught by the reference and recited by the instant invention (see for example, US 5,869,677, col. 5, lines 57-64; US 5,874,273, col. 6, lines 28-31).

For this reason and those given in the previous Office Action, the rejection of claims 50, 55, 57 and 59 under 35 USC 103(a) over Daynes et al. (US 5,532,230) is maintained.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Telephone Inquiry

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
October 18, 2005